DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 4, 2014

Medicrea International
Mr. David N. Ryan
Director Marketing & Product Development
14 Porte du Grand Lyon
Neyron 01700
France

Re: K140738
Trade/Device Name: PASS LP Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP, OSH
Dated: September 22, 2014
Received: October 1, 2014

Dear Mr. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140738

Device Name
PASS LP Spinal System

Indications for Use *(Describe)*
The PASS LP Spinal Systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fracture
- Dislocation
- Failed previous fusion (Pseudarthrosis)
- Spinal stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformities such as scoliosis or kyphosis
- Loss of stability due to tumors

The PASS LP Spinal Systems are also indicated for pedicle screw fixation for the treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants fate the attainment of a solid fusion.

The PASS LP also includes hooks and rods and sacral/iliac screws indicated for degenerative disc disease (DDD) defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis and failed previous fusion.

Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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**510(k) SUMMARY**

**MEDICREA INTERNATIONAL's PASS LP Spinal System**

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the PASS LP Spinal System – Patient Specific (UNiD) Rods.

Date Prepared: 03 November 2014

1. **Submitter:**

MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700
FR

**Contact Person:**

Audrey VION
MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700
FR

2. **Trade name:** PASS LP Spinal System

   **Common Name:** Spinal Fixation Appliances

   **Classification Name:** Pedicle Screw Spinal System §888.3070

   **Classification and Regulation:** Class II

   MNI: orthosis, spinal pedicle fixation
   MNH: orthosis, spondylolisthesis spinal fixation
   KWP: appliance, fixation, spinal interlaminal
   OSH: pedicle screw spinal system, Adolescent Idiopathic Scoliosis

3. **Primary Predicate or legally marketed devices which are substantially equivalent:**
   - PASS LP Spinal System, (MEDICREA INTERNATIONAL, K123138)

4. **Description of the device:**

The UNiD Rods have to be used with the PASS LP Spinal System designed to contribute to correction and surgical stabilization of the thoracic, lumbar and sacral spine.

The system consists of pedicle screws, hooks, sacral plates, iliac screws, clamps, rods, nuts, rod plates and crosslink components. It can be used for single or multiple level fixations. Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 or cobalt-chromium molybdenum alloy Co-Cr28Mo6 that conforms to ISO 5832-12 and ASTM F1537.

The purpose of this submission is to add to the PASS LP range the new component: ' Patient Specific Rod'. The Patient Specific Rod is a rod bent before the surgery by MEDICREA, following the design defined by the surgeon only, specific to a unique patient.

A subset of PASS LP Spinal System components may be used for posterior pedicle screw fixation. These constructs may be comprised of a variety of shapes and sizes of rods, hooks, sacral hooks, sacral plates, iliac screws, clamps, nuts and crosslink components. These

components can be rigidly locked into a variety of configurations, with each construct being tailored made for the individual case.

**Materials:** Titanium alloy and Cobalt-chromium-molybdenum alloy

**Function:** The PASS LP was developed as an implant:
• To provide immobilization and stabilization of posterior spinal segments
• to augment the development of a solid spinal fusion
• to provide stability to ease fusion
• to be mechanically resistant to allow the fusion of the operated level

## 5. Intended Use

The PASS LP Spinal Systems include a pedicle system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar, and sacral spine:

- Fractures
- Dislocation
- Failed previous fusion (Pseudarthrosis)
- Spinal stenosis
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Spinal deformations such as scoliosis or kyphosis.
- Loss of stability due to tumors.

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Except for rod plates, when used for posterior non-cervical pedicle screw fixation in pediatric patients, the PASS LP Spinal System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The PASS LP Spinal System is intended to be used with allograft and/or autograft. Pediatric pedicle screw fixation is limited to a posterior approach.

## 6. Substantial equivalence claimed to predicate devices

The primary predicate device used to demonstrate SE is the PASS LP Spinal System (K123138). The UNiD Rods are substantially equivalent to the already cleared PASS LP pre-bent rods in terms of intended use, materials used, mechanical safety and performances

The table below compares the features and characteristics of UNiD Rods to their predicate devices.

| Device | MEDICREA INTERNATIONAL Patient Specific Rods | PASS LP Pre-bent Rods (MEDICREA INTERNATIONAL) | PASS LP Straight Rods (MEDICREA INTERNATIONAL) |
|---|---|---|---|
| 510(k) number | Unknown | K123138 | K123138 |
| **Intended use** | | | |
| Thoracic | Yes | Yes | Yes |
| Lumbar | Yes | Yes | Yes |
| Design | | | |
| Diameters | Ø5.5 and Ø6 mm | Ø5.5 and Ø6 mm | Ø5.5 and Ø6 mm |
| Lengths | 30 mm à 500 mm | 30 à 180mm | 30 à 600mm |
| Curvatures | Directly adapted to the operated patient. No need of additional bending during surgery | Pre-Bent, but will need to be bent to be adapted to the patient anatomy during the surgery. | Straight so need to be bent to be adapted to the patient anatomy during the surgery. |
| **Materials** | | | |
| | Ti-6Al-4V (ASTM F136 & ISO 5832-3)<br>Or Co-Cr 28Mo6 alloy 1 (following the ASTMF1537 and ISO 5832-12) | Ti-6Al-4V (ASTM F136 & ISO 5832-3) | Ti-6Al-4V (ASTM F136 & ISO 5832-3)<br>Or Co-Cr 28Mo6 alloy 1 (following the ASTMF1537 and ISO 5832-12) |

**7. Non-clinical Test Summary:**

For the UNiD rods , static and dynamic compression and static torsion tests following the ASTM F1717 were conducted on two worst cases: one on UNiD Rods with an extreme lordosis and this other one with an extreme kyphosis.

No test was conducted following the ASTM F1798, because this standard described a way to test the connection components of a system in sliding. MEDICREA INTERNATIONAL UNiD Rods have the same diameters as the already cleared PASS LP rods (diameter) the contact area between the UNiD Rods and the different connectors of the ranges is strictly identical. Therefore the results obtained following this standard with the already cleared PASS LP components are still are valuable for the PASS LP Patient Specific Rods.

**8. Clinical Test Summary**

No clinical studies were performed

**9. Conclusions Non clinical and Clinical**

The UNiD Rods or Patient Specific Rods are substantially equivalent to its predicate devices in terms of indications for use, design, material, mechanical performances and function.